DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
g1097d

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

01-PHI-10

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

April 5, 2001

Daniel F. Stoltzfus, Owner
Stoltzfus Kountry Kitchen
3612 East Newport Road
Intercourse, Pa 17534

Dear Mr. Stoltzfus:

Inspections of your acidified processing plant, Stoltzfus Kountry Kitchen, located At 3612 East Newport Road, Intercourse, PA conducted by Investigator Calvin W. Edwards of the Food and Drug Administration (FDA) between July 12 Through August 8, 2000 and November 7 and 8, 2000 revealed serious deviations from Title 21 of the Code of Federal Regulations (21 CFR), Part 108 and 114, Emergency Permit Control and Acidified Foods. These deviations cause acidified Butter Beans, Red Beets, Pickled Red Spiced Beets, Pickled Red Beet Eggs, Hot Spiced Eggs and Marinated Mushrooms manufactured by our firm to be adulterated within the meaning of section 402(a)(4) of the Food Drug and Cosmetic Act (the Act), in that they have been prepared, packed or held under conditions whereby they may have become injurious to health, as follows:

> Your firm must establish a scheduled process, including a safe pH level, for each acidified food as required by 21 CFR 114.80(a)(1). However, a review of your firm's batch records (recipe information sheet) for butter beans lot [redacted] manufactured on April 20, 2000 and lot [redacted] manufactured on April 26, 2000 revealed the brine pH product specification was 4.7. A review of the recipe information sheets for butter beans batch [redacted] manufactured on April 20, 2000 indicated a measurement for brine pH of 4.7.

You must routinely measure equilibrium pH for acidified products as required by 21 CFR 114.80(a)(2). However, during the inspection ending August 8, 2000, a review of the recipe information sheets for butter beans Batch [redacted] manufactured on April 20, 2000 indicated no equilibrium pH measurement. The Recipe Information Sheet for butter beans, Batch [redacted] produced on April 26, 2000 did not record the equilibrium pH. Other instances where your firm did not measure equilibrium pH are noted below:

[redacted] out of [redacted] records reviewed for Hot Spiced Eggs, lots, [redacted] and [redacted] do not show any value for equilibrium pH.

[redacted] out of [redacted] records reviewed for Sweet Baby Corn, lots, [redacted] and [redacted] do not show any value for equilibrium pH.

[redacted] out of [redacted] records reviewed for Red Beet Eggs, lots, [redacted] and [redacted] do not show any value for equilibrium pH.

[redacted] out of [redacted] records reviewed for Red Beets, lots, [redacted] and [redacted] do not show any value for equilibrium pH.

A commercial processor shall not later than 10 days after first so engaging in manufacturing and packing of acidified foods, register and file with the FDA on form FDA 2541a in accordance with 21 CFR 108.25(c)(1). In addition, a commercial processor engaged in the processing of acidified foods shall not later than 60 days before packing any new product, provide the FDA information on the scheduled processes. This shall include, as necessary, conditions for heat processing and control of pH and source and establishment of the process, for each acidified food in each container size in accordance with the requirements set forth in 21 CFR 108.25(c)(2). Our records indicate that a Philadelphia District Compliance Officer has previously advised you of this requirement.

You failed to identify process deviations, maintain a separate process deviation file and evaluate the product for any possible bearing on public health as required by 21 CFR Part 114.89 and 21 CFR Part 114.100(c). In addition, you failed to promptly notify FDA of process deviations as required by 21 CFR Part 108.25(d). During the inspection ending August

8, 2000 and the inspection ending November 8, 2000, the following process deviations were observed as follows:

A review of the recipe information sheets for butter beans, lot [redacted] and [redacted] manufactured on April 20, 2000 and April 26, 2000, respectively, revealed a brine pH of 4.7 and no equilibrium pH. The batches of butter beans noted above were shipped in a commingled lot to a retailer who notified your firm that there was a problem with the product. The butter beans were returned to your firm and destroyed. Your firm was not able to account for the disposition of [redacted] of the 12/12oz butter beans.

A review of the recipe information sheet for sweet baby corn, batch [redacted] revealed that your firm had changed its formula for this product from gallons to pounds. During this period, they discovered on June 16, 2000 that the batch produced on April 13, 2000 contained 4 pounds of vinegar instead of 4 gallons of vinegar. The batch record indicates your manager approved this deviation.

A review of the recipe information sheets for Red Beets, batches [redacted] and [redacted] show that cook times vary from batch to batch.

A review of the recipe information sheets for Red Beet Eggs, batches [redacted] indicate the amount of ingredients added is inconsistent.

A review of the recipe information sheets for spiced red beets, lot [redacted] manufactured on September 7, 2000 and red beets, lots [redacted] and [redacted] manufactured on September 13, 2000 and September 21, 2000, respectively, revealed that canner time and temperature were not recorded on the batch records.

Further, you failed to routinely record processing information as required by 21 CFR Part 114.100(a). For example:

A review of the recipe information sheet for Butter Beans produced on April 26, 2000 indicated a failure to record canner temperature, canner time, equilibrium pH, and product temperature and brine temperature.

A review of the recipe information sheets for Hot Spiced Eggs

produced on January 20, 2000 indicated a failure to record the canner temperature, equilibrium pH and product temperature.

A review of the recipe information sheets for Hot Spiced Eggs produced on March 16, 2000 indicated a failure to record canner temperature, canner time, equilibrium pH, product temperature, brine temperature, product code and the ingredient jalapeno peppers.

A review of the recipe information sheet for spiced red beets produced on September 7, 2000 indicated a failure to record canner time and temperature.

A review of the recipe information sheets for red beets produced on September 13, 2000 and September 21, 2000 indicated a failure to record canner time and temperature.

Additionally, you failed to maintain processing and production records, for the above noted products, that show adherence to scheduled processes, which include records of pH measurements and other critical factors intended to ensure a safe product. They must be maintained and contain sufficient additional information such as product code, date, container size, and product, in order to permit a public health hazard evaluation of the processes applied to each lot, other portion of production as required by 21CFR Part 114.100 (b).

You failed to manufacture acidified products under the supervision of a person who has attended a Commissioner approved school as required by 21 CFR Part 108.25(f) and 21 CFR Part 114.10. On July 12, 2000 and July 21, 2000, acidified foods were being produced. You are the only graduate of a Commissioner approved school, and you were not present during production.

Your firm's processes have not been established by a qualified person who has expert knowledge in the acidification and processing of acidified foods as required by 21 CFR Part 114.83. Your firms manager, the person identified as responsible for product and process development, has not attended a Commissioner approved school.

At the conclusion of the August 2000 and the November 2000 inspections, you were presented with form FDA-483's listing serious deviations from the regulations. During the inspection ending August 8, 2000, after the investigator reviewed the first observation with you, you informed him that you did not have time to discuss the other observations.

You are reminded a previous FDA inspection conducted on January 12, 25 and 27, 1999, found similar deficiencies. The FDA is concerned that in over two years, your firm has not taken action to correct these deficiencies.

You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure, injunction and/or the issuance of an order requiring a permit before delivery of introduction or introducing your acidified products into interstate commerce. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please notify this office in writing within fifteen (15) working days from your receipt of this letter of the specific things that you are doing to correct these deviations. You may wish to include in your response documentation that would be useful in assisting us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Emergency Permit Control regulations (21 CFR Part 108), the Acidified Food regulations (21 CFR Part 114) and the Good Manufacturing Practice regulations (21 CFR Part 110).

You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug and Cosmetic Act and all applicable regulations.

Your response should be sent to Lynn S. Bonner, Compliance Officer at the address noted above.

Sincerely,

Margaret E Egan

for Thomas D. Gardine
District Director
Philadelphia District

lsb

cc: Pennsylvania State Department of Agriculture
Bureau of Food Safety and Laboratory Services
2301 North Cameron Street
Harrisburg, PA 17110-9408
Attention: Lenchen H. Radle, Chief Food Safety Division